

## Drug Listing Working Group meeting June 9, 2010

### Agenda

#### **SPL**

- Quantity Denominator value in Packaging Section of Drug Listing SPL - Jean
  - FDA validation rule states the number shall be "1", but I just successfully submitted an SPL file with lowest pack level quantity denominator of "1.0" and second pack level of "1". Why were all accepted? What is the team's feedback?
  - **ACTION: Pat to check with Lonnie to see if validation rule is not turned on.**
  
- Update from Lead Team May 5 - Pat
  - Validation rules have been updated
    - o Validation rules now require medication guides for those labels required to have medication guides.
    - o Medication guides need to be coded correctly- FDA will call you if they are not coded correctly.
  - Link in the access database....having issues with activating links. Should be up and running by June.
  - HL7 changes for new schema have been communicated. The main concern is lack of backward compatibility with R4. Implementation will not occur before the end of this year though. A write up by Keith Thomas will be shared with the SPL technical team.
  
- Business operation terms - Pat
  - Terms intended to be used only by 3<sup>rd</sup> party manufacturers:
    - o Pack, Label, Sterilize
    - o Don't have to include these terms if the parent company is doing these operations – even at another manufacturing site that is registered as a manufacturer. Just include the term manufacturer.
    - o **ACTION: Pat to clarify with FDA the level of detail necessary related to specific operations at a site.**

#### **Submissions/Gateway**

- Michael Fauntleroy's email regarding the gateway (attached) – Ruth
  - Discuss how companies are handling the storage of their receipts and acknowledgements and to ensure everyone has been made aware of this deadline.
    - o Some companies received this same notice (to move acknowledgements immediately). Two companies move files to archive location once SPL is posted or immediately after sending.
    - o Sponsors should check to see if they received this notice from M. Fauntleroy.
    - o Most companies receive second acknowledgements within 1-2 days of submission. One company did not receive a second acknowledgement for 4 months.

- Does new approval letter language impact how submissions are handled? – Jess
  - CBEs, sNDAs – send SPL to Review Division, with a separate submission to OC? Submit to eLIST within 14 days?
    - o The concern is, if one submits to eLIST only, it will be left out of the eCTD leaf.
    - o Try to work it out with Review Division ahead of letter being issued.

### **FEIs**

- Would a FEI # be transferred with a change of ownership? – Michelle
  - Experience is FEI # would be transferred.
  - Some companies have experienced the DUNS being transferred also. It all depends on how the company handles the change with D&B.
  - If you transfer the FEI – all history should be transferred theoretically.
  - The team doesn't think the FEI number has a validation rule. Theoretically then, two separate establishments can be registered with the same FEI.
  - A Distributer does not need a FEI number.
  - (fyi) Official email received yesterday from DRLS with FEI number – Jean

### **Next meeting agenda:**

- Follow-up from Perrigo requested - Kathy
- Follow-up from Roche requested - Kerry

### **For your Information**

Imports Template Posted on WIKI -

<http://spl-work-group.wikispaces.com/Import+Q-and-A#Import-Letter>